REMARKS

Claims 1–8 and 10–16 are pending in this application. By this Amendment, claims 1–8 and 10–14 are amended, claim 9 is canceled, and claims 15 and 16 are added. Support for the amendments to the claims can be found, for example, in the original claims and the specification. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Rejection of Claim 9 Under 35 U.S.C §102

The Office Action rejects claim 9 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,878,827 to Ono et al. ("Ono"), U.S. Patent No. 6,350,869 B1 to Sturm et al. ("Sturm"), U.S. Patent No. 4,559,334 to Takaya et al. ("Takaya '334"), and U.S. Patent No. 4,935,507 to Takaya et al. ("Takaya '507"). Claim 9 has been canceled, rendering the rejection moot.

II. Rejections of Claim 14 Under 35 U.S.C §102

A. Lee

The Office Action rejects claim 14 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,093,814 to Lee et al. ("Lee"). Applicants respectfully traverse the rejection.

Without conceding the propriety of the rejections, independent claim 14 is amended to more clearly recite various novel features of the claimed invention, with particular attention to the Examiner's comments. Specifically, independent claim 14 is amended to clarify that M^+ represents a counter sodium ion or potassium ion. Support for the amendments to claim 14 can be found in the specification, for example, at page 9, lines 6 and 7. Lee does not expressly or inherently describe such a feature.

Lee does not anticipate claim 14. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Kameyama

The Office Action rejects claim 14 under 35 U.S.C. §102(b) as being anticipated by WO 01/7921 to Kameyama ("Kameyama"). Applicants respectfully traverse the rejection.

Kameyama does not expressly or inherently describe a counter sodium ion or potassium ion, as required by claim 14, as amended. Therefore, Kameyama cannot be said to anticipate claim 14.

Kameyama does not anticipate claim 14. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Rejection under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 1–6, 10, and 12 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been amended in light of the Examiner's comments, as follows:

1. Variable X is now defined in claim 1. Support for this amendment may be found in the specification, for example, at page 8, lines 23–24.

2. Iminium has been removed from claim 2.

3. Claim 2 is amended to clearly recite that the first two choices for X are functional groups.

4. Claim 3 has been amended to recite ions and not free molecules.

5. The phrase "and the like" has been removed from claims 4, 6, and 12.

6. In claims 5, 6, and 12, the recitation of "organic solvent" is amended to recite "solvent." Clearly, the recitation of the choice "water" supports the amendment.

7. Variable M is now defined in claim 10. Support for this amendment may be found in the specification, for example, at page 9, lines 6–11.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

IV. Claim Objections

The Office Action objects to claim 9 for an informality. Claim 9 is canceled, thus rendering the rejection moot.

V. New Claims

By this Amendment, new claims 15 and 16 are presented. New claims 15 and 16 are directed to an amorphous hydrate of cefdinir, which was the subject matter of canceled claim 9, and more clearly recites the various novel features of the claimed product by use of a product-by-process claim structure.

As in canceled claim 9, claims 15 and 16 are directed to an amorphous monohydrate of cefdinir. The Office Action correctly points out that Ono and Sturm are silent as to whether its compounds are amorphous. The Office Action asserts that the "amorphous" characteristic as claimed is inherently present in the compounds taught by the applied references. Applicants respectfully disagree.

In order to overcome a presumption of inherency, an applicant needs to establish that a prior art product does not necessarily possess the characteristics of the claimed composition. The characteristic in question is "amorphous." As the Examiner notes, "an amorphous material" is "not a crystalline product."

Therefore, any showing that there exists a crystalline form of cefdinir with the same structural formula as recited in claims 15 and 16 would prove that the characteristic of being "amorphous" is not an inherent property. Takaya '507, in column 1, lines 1–19, discloses a crystalline compound having the same formula as recited in claims 15 and 16. Therefore, the characteristic of being "amorphous" as required by claims 15 and 16 is not an inherent property of the composition represented by formula (I). Accordingly, any reference that does

not expressly describe a compound with the same structural formula as being amorphous cannot anticipate, and would not have rendered obvious, claims 15 and 16. As conceded by the Office Action, Ono and Sturm are both silent in this respect. Therefore, neither Ono nor Sturm anticipate, or would have rendered obvious, claims 15 and 16.

On the other hand, as acknowledged by the present application, Takaya '507 describes some of its products described in Takaya '334 as "crystalline like amorphous." *See*, Specification at page 1, lines 19–23. However, the inventors present evidence in the specification as to how their product obtained by the methods claimed is different from the product obtained according to the teachings of Takaya '334, such as differences in yield and purity. *See*, Specification at page 2, lines 4–13, and Examples.

Those skilled in the art would appreciate that the nature of crystallization of any active pharmaceutical ingredient (API) depends on the temperature and/or mode of pH adjustment during crystallization. The amorphous form of cefdinir monohydrate is obtained either by adjusting the pH to acidic condition at 10°C to 40°C followed by rapid cooling to -10°C to -40°C, or by cooling the reaction mass to -40°C to 0°C followed by rapid addition of acid to lower the pH. *See, e.g.*, Specification at page 10, lines 14–20, and Examples 1–4. None of the cited references *per se* follow these methods. Therefore, one cannot arrive at the compositions of claims 15–16 through the guidance provided by the applied references.

For the foregoing reasons, it is believed that claims 15 and 16 are patentable over the applied references. Prompt examination and allowance of new claims 15 and 16 are respectfully requested.

VI. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1–8 and 10–16 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

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